No. 96-1405

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
Petitioner,

v.

SARAH KERNATS, a minor, by CYNTHIA KERNATS, her mother and next friend, CYNTHIA KERNATS, individually, and ANDREW KERNATS,
Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
Petitioner,

v.

JOYCE OSHODI, individually and as mother and next friend of KENNETH OSHODI, a minor,
Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
Petitioner,

v.

MARY SUSAN WILLIAMS, as mother and next friend of JOHN CALVIN WILLIAMS, a minor,
Respondents.

On Petition for Writ of Certiorari to the Appellate Court of Illinois, First District

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REPLY BRIEF IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES ii

REASONS FOR GRANTING THE WRIT 1

I.

THE RECENT DECISIONS OF TWO FEDERAL APPELLATE COURTS HAVE INTENSIFIED THE CONFLICT AMONG THE LOWER COURTS REGARDING THE SCOPE OF MDA PREEMPTION 1

II.

THE DIVISION OF AUTHORITY REGARDING MDA PREEMPTION WILL CONTINUE TO GROW UNLESS THIS COURT RENDERS A CONCLUSIVE DECISION 4

III.

THE ILLINOIS APPELLATE COURT ERRONEOUSLY DEFINED THE SCOPE OF MDA PREEMPTION AS IT RELATES TO IDE AND PMA CLASS III MEDICAL DEVICES 5

CONCLUSION 9

TABLE OF AUTHORITIES

Cases PAGE

Armstrong v. Optical Radiation Corp., 57 Cal. Rptr. 2d 763 (Cal. Ct. App. 1996) 3

Chambers v. Osteonics Corp., ___ F.3d ___, 1997 WL 155113 (7th Cir. 1997) 1, 2

Connelly v. Iolab Corp., 927 S.W.2d 848 (Mo. 1996) 2

Medtronic, Inc. v. Lohr, 116 S.Ct. 2240 (1996) . *passim*

Papike v. Tambrands, Inc., 107 F.3d 737 (9th Cir. 1997) 2, 3, 8

Walker v. Johnson & Johnson Vision Products, Inc., 217 Mich. App. 705 (1996) 3

REPLY BRIEF IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

Petitioner, Smiths Industries Medical Systems, Inc. ("SIMS"), respectfully submits this Reply Brief in Support of its Petition for Writ of Certiorari to the Appellate Court of Illinois, First District.

REASONS FOR GRANTING THE WRIT

I.

THE RECENT DECISIONS OF TWO FEDERAL APPELLATE COURTS HAVE INTENSIFIED THE CONFLICT AMONG THE LOWER COURTS REGARDING THE SCOPE OF MDA PREEMPTION.

SIMS established in its Petition for Writ of Certiorari that the lower courts have been unable to consistently apply this Court's decision in *Medtronic, Inc. v. Lohr*, 116 S.Ct. 2240 (1996). Within the past two months alone, the decisions of two Federal Appellate courts have widened the division of authority.

In *Chambers v. Osteonics Corp.*, ___ F.3d ___, 1997 WL 155113 (7th Cir. April 3, 1997), the United States Court of Appeals for the Seventh Circuit held in favor of preemption in a case involving an IDE Class III medical device. The plaintiff in *Chambers* brought a products liability action against the manufacturer of a Class III hip prosthesis that had been granted an IDE by the FDA. 1997 WL 155113 at *1.

The Seventh Circuit in *Chambers* held that the plaintiff's claims based on strict products liability and breach of implied warranty "could impose liability on [the manufacturer] for an experimental device that meets all FDA

standards and requirements but is still somehow adjudged unreasonably dangerous." *Id.* at *5. The Seventh Circuit further held that upholding the plaintiff's claims would "defeat the purpose of the investigational device exemption" and "set up a direct collision with Federal policy". *Id.* Accordingly, the Seventh Circuit held that the plaintiff's strict products liability and breach of implied warranty claims were preempted by the MDA.[1] *Id.*

The Seventh Circuit's decision in *Chambers* directly conflicts with the *Kernats* decision below, where the Illinois Appellate Court held that preemption does not apply to the Plaintiffs' strict liability and breach of implied warranty claims. The Seventh Circuit's decision in *Chambers* also conflicts with the decision of the Supreme Court of Missouri in *Connelly v. Iolab Corp.*, 927 S.W.2d 848, 853-54 (Mo. 1996). In *Connelly*, a case involving an IDE Class III device, the court held that the plaintiff's strict liability claim was not preempted.

The recent decision of the United States Court of Appeals for the Ninth Circuit in *Papike v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir. February 20, 1997), has also contributed to the split of authority regarding MDA preemption. In *Papike*, the plaintiff brought suit against the manufacturer of a tampon (a Class II device) for failure to warn of the risk of toxic shock syndrome. The plaintiff argued that her failure to warn claim was not preempted by the MDA because her claim arose from "generally applicable" principles of state tort law that were not spe-

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[1] The court held that the plaintiff's claim for negligent manufacturing was not preempted to the extent it was based on requirements that mirrored the requirements imposed by the MDA and the FDA.

cifically developed "with respect to" medical devices. *Id.* at 741.

The Ninth Circuit rejected the plaintiff's argument as inconsistent with this Court's decision in *Medtronic*. *Id.* at 741-42. The Ninth Circuit held that state law products liability claims are *not* immune from preemption merely because they arise from requirements applicable to all product manufacturers. *Id.* Rather, the Ninth Circuit held that generally applicable state law requirements *are* subject to preemption when they impose requirements that exceed or differ from specific Federal requirements. *Id.* Based on the existence of specific Federal requirements regarding tampon labeling, the Ninth Circuit concluded that the plaintiff's failure to warn claim was preempted by the MDA. *Id.*

Although *Papike* involved a Class II medical device, the Ninth Circuit's decision in that case directly conflicts with the Illinois Appellate Court's decision in *Kernats*. The basic holding underlying the *Papike* decision is that MDA preemption *does* apply to "generally applicable" state law tort claims. However, the Appellate Court in *Kernats* held that the Plaintiffs' state law tort claims are not preempted because they arise from "general duties applicable to every manufacturer". (App. at 14-16).

The Ninth Circuit's decision in *Papike* also conflicts with *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Cal. Ct. App. 1996), and *Walker v. Johnson & Johnson Vision Products, Inc.*, 217 Mich. App. 705 (1996). In both *Armstrong* and *Walker*—cases involving PMA Class III devices—the courts held that the plaintiffs' claims were not preempted because they arose from generally applicable state tort law.

II.

THE DIVISION OF AUTHORITY REGARDING MDA PREEMPTION WILL CONTINUE TO GROW UNLESS THIS COURT RENDERS A CONCLUSIVE DECISION.

This Court's grant of certiorari in *Medtronic, Inc. v. Lohr* provides ample proof that MDA preemption involves significant legal *and* social issues. However, the decisions cited by SIMS in its Petition and in this Reply Brief clearly demonstrate that the lower courts desperately require additional guidance from this Court.

Critical questions regarding the scope of MDA preemption remain unanswered. Does MDA preemption apply to claims that challenge the safety and effectiveness of IDE Class III devices? Of PMA Class III devices? Are product liability claims immune from preemption because they arise from "generally applicable" duties applicable to all product manufacturers? The foregoing questions are not rhetorical. The lower courts will continue to struggle with those questions unless this Court intervenes and renders a conclusive decision.

The instant Petition is *ideally* suited for acceptance by this Court. It is undisputed that the CVS catheter in controversy was first granted an IDE, and was subsequently granted PMA. Thus, this Court can conclusively resolve *in one decision* the scope of preemption as it relates to IDE Class III devices *and* PMA Class III devices, and thereby put an end to the growing number of conflicting lower court decisions.

The opportunity to resolve these unanswered questions *in one decision* will not likely present itself to this Court again. Therefore, this Court should grant SIMS' Petition for Writ of Certiorari.

III.

THE ILLINOIS APPELLATE COURT ERRONEOUSLY DEFINED THE SCOPE OF MDA PREEMPTION AS IT RELATES TO IDE AND PMA CLASS III MEDICAL DEVICES.

In opposition to SIMS' Petition, Plaintiffs do not dispute the existence of the conflict among the lower courts regarding MDA preemption. Nor do Plaintiffs dispute the legal and social importance of MDA preemption. Nor do Plaintiffs dispute that the CVS catheter in controversy was granted both an IDE and PMA.

Rather, in opposition to SIMS' Petition, Plaintiffs merely argue that the decision of the Illinois Appellate Court below was correct. As set forth below, however, Plaintiffs' arguments in that regard are erroneous.

In defending the Appellate Court's decision in *Kernats*, Plaintiffs have asserted arguments that were explicitly rejected *in the Kernats opinion*. For example, Plaintiffs argue that the MDA does not preempt their claims because there are no "specific" Federal requirements applicable to the SIMS CVS catheter. (Plaintiffs' Brief at 6). However, the Appellate Court in *Kernats* expressly held that the requirements of the premarket approval process *are* sufficiently specific to trigger preemption. (App. at 13).

Plaintiffs also argue that their claims are not preempted because MDA preemption applies only to legislatively enacted statutes and regulations, and was not intended to encompass state law tort claims. (Plaintiffs' Brief at 7). However, the Illinois Appellate Court in *Kernats* expressly rejected the argument that state tort law claims can never be preempted. (App. at 10). In fact, the Appellate Court in *Kernats* correctly held that in

Medtronic a majority of this Court's Justices held that the scope of MDA preemption *does* encompass state law tort claims. (App. at 10).

The basis of the *Kernats* decision—and the basic flaw in that decision—is the Appellate Court's conclusion that the Plaintiffs' claims of negligence, strict liability and failure to warn are not preempted because those claims arise from "general duties applicable to every manufacturer." (App. at 14). In reaching that conclusion, the Appellate Court erroneously relied on an isolated portion of the *Medtronic* opinion that was *rejected by a majority of this Court's Justices*.

Specifically, the Appellate Court in *Kernats* relied on a *single paragraph* of Section V of Justice Stevens' plurality decision in *Medtronic*, where Justice Stevens, writing for himself and only three other members of this Court, stated that the Lohrs' claims for negligent manufacturing and negligent failure to warn were not preempted because they "were not specifically developed 'with respect to' medical devices." *Medtronic*, 116 S.Ct. at 2258. There, Justice Stevens wrote as follows:

> The predicate for the Lohrs' negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. . . . These State requirements therefore escape preemption, not because the source of the duty is a judge-made or common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k

> envisioned to be "with respect to" specific devices such as pacemakers.

Id.

Although the Appellate Court in *Kernats* relied on the foregoing passage from Justice Stevens' opinion, (App. 14-15), a close reading of the *Medtronic* opinion *in its entirety* reveals that a majority of this Court's Justices rejected Justice Stevens' view regarding the preemption of "general" common law duties. Writing for herself and three other Members of this Court, Justice O'Connor explicitly rejected Justice Stevens' view. *Id.* at 2262-64. In no uncertain terms, Justice O'Connor held that the Lohrs' "general" claims for negligent manufacturing and failure to warn *were* preempted. *Id.*

Justice Breyer, who wrote a separate opinion concurring in part and concurring in the judgment, broadly held that common law claims, *under certain circumstances*, may be preempted by the MDA. *Id.* at 2259. Justice Breyer then clarified that holding, explaining that common law claims are preempted only when there are "specific" *federal* requirements applicable to the medical device in controversy. *Id.* at 2260-61 (citing 21 C.F.R. §808.1(d)).

Significantly, Justice Breyer did *not* hold that preemption occurs only when the common law claims at issue are also device-specific. Rather, Justice Breyer held that the need for specificity applies only to the *federal* requirements at issue. *Id.* at 2261. Thus, unlike Justice Stevens, Justice Breyer did *not* hold that "general" state law requirements, such as those arising from common law negligence claims, escape preemption. In fact, Justice Breyer expressly held that a negligence claim brought

against a medical device manufacturer would be subject to preemption in the presence of a conflicting specific federal requirement. *Id.* at 2259.

Significantly, in the recent decision in *Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. February 20, 1997), the Ninth Circuit held that Justice Breyer *disagreed* with Justice Stevens' view regarding the preemption of generally applicable tort law claims. In *Papike*, the Ninth Circuit held that a "fair reading" of Justice Breyer's separate opinion reveals that Justice Breyer concluded that generally applicable tort law claims can be preempted. In that regard the Ninth Circuit held as follows:

> It makes little sense to argue that Justice Breyer would write separately to make clear his position that duties arising under state common law can constitute state law "requirements" which can be preempted by the MDA, and then agree that because tort law consists of generally applicable principles, it is always preempted, even in the face of specific federal requirements. Instead, in *Medtronic* Justice Breyer found "no actual conflict between any federal requirement and any of the liability-creating-premises of the plaintiffs' state law tort suit." (Citing *Medtronic* at 2261). Here, there would be such a conflict. Part of Papike's claim is that the federal requirements do not suffice, and that Tambrands should be required to, among other things, add a variety of warning statements not required by the federal regulation. As Justice Breyer explained, these are "the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." (Citing *Medtronic* at 2259).

Papike at 742.

Thus, despite Justice Breyer's agreement with *certain* aspects of Justice Stevens' opinion, Justice Breyer clearly rejected Justice Stevens' view that the MDA does not preempt claims based on general common law duties. As stated above, four other Justices—comprising a majority of five Justices—also rejected Justice Stevens' "general duty" holding. Therefore, the Appellate Court in *Kernats* misapplied the *Medtronic* opinion by finding against preemption based on the general nature of the common law duties underlying the Plaintiffs' claims.

In summary, to *conclusively* resolve the sharp division among the lower courts regarding the scope of MDA preemption, to ensure the availability of life-saving and life-enhancing medical devices, and to correct the erroneous decision of the Appellate Court in *Kernats*, this Court should grant SIMS' Petition for Writ of Certiorari.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

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